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November 15, 2019

VIA CM/ECF

The Honorable Maryellen Noreika
United States District Court for the District of Delaware
844 N. King Street
Wilmington, DE 19801

Re: *Biogen International GmbH, et al. v. Amneal Pharmaceuticals LLC, et al.*,
Civil Action No. 17-823-MN (Consolidated)

Dear Judge Noreika:

We, along with Finnegan, Henderson, Farabow, Garrett & Dunner LLP, represent Biogen International GmbH and Biogen MA Inc. ("Plaintiffs") in the above-mentioned action. Pursuant to the Court's November 13, 2019 Oral Order, (D.I. 329), requesting a joint submission setting the issues that remain for trial, the amount of time the parties believe is necessary for trial, and the parties' availability to begin trial during the week of December 2, 2019, the parties jointly submit the following:

I. The issues that remain for trial:

- A. Invalidity of U.S. Patent No. 8,399,514 ("the '514 Patent")
 - 1. § 102 for anticipation, derivation, and improper inventorship;
 - 2. § 103 for obviousness; and
 - 3. § 112 for lack of written description and enablement.
- B. Aurobindo's Infringement of the '514 Patent

II. The amount of time the parties believe is necessary for trial:

- A. Plaintiffs' Position: Plaintiffs believe that, considering the nature and extent of the parties' disputes, a total of 54 hours is necessary for trial.

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1. Validity: Plaintiffs believe that 50 hours¹ is necessary for trial of the '514 patent validity issues and request that 50 hours be split evenly between Plaintiffs and Defendants to address validity (25 hours for Plaintiffs; 25 hours for Defendants). Defendants are asserting six different, complex invalidity theories (see Section I.A.(1)-(3) above).
 2. Infringement: Plaintiffs believe that 4 hours is necessary for trial of the '514 patent infringement issues and request that 4 hours be split evenly between Plaintiffs and Defendant Aurobindo (2 hours for Plaintiffs; 2 hours for Aurobindo).
- B. Defendants' Position: Defendants believe that, considering the nature and extent of the parties' disputes, a total of 30 hours is necessary for trial.
1. Invalidity: Defendants believe that a total of 30 hours is necessary for trial on all of the invalidity issues of the '514 patent.² There is only one disputed patent for trial. Defendants' invalidity theories under 35 U.S.C. §§ 102, 103, and 112 rely on overlapping facts. Defendants request that the 30 hours be split evenly between Plaintiffs and Defendants to address invalidity (15 hours for Plaintiffs; 15 hours for Defendants).
 2. Defendant Aurobindo's Noninfringement: Defendant Aurobindo does not anticipate that infringement will be contested at trial. To the extent that infringement still remains an issue for Aurobindo, Defendants propose that the noninfringement issue be bifurcated and can be scheduled at a different time than the trial of invalidity, if necessary.
- III. The parties' availability to begin trial during the week of December 2, 2019:
- A. Joint Short Response: Although the parties have not yet heard back from every witness, the parties have received sufficient responses from their respective expert and fact witnesses to report that neither side is able to begin trial during the week of December 2, 2019. However, the parties remain available to begin trial the week

¹ Plaintiffs note that until November 14, 2019 there were two patents at issue in this consolidated action, the '514 patent and U.S. Patent No. 7,619,001 ("the '001 patent"). The proposed estimated trial times exchanged with Defendants' prior to November 14, 2019 included a separate allocation of time for the trial issues related to the '001 patent. Given the overlapping technology of the '001 patent, which also involved a treatment for multiple sclerosis, Plaintiffs needed to add the time allocated for the '001 patent back to the total amount of time needed for trial.

² As recently as Wednesday, November 13th, after the Court's Oral Order (D.I. 329) issued, Plaintiffs had proposed to Defendants that all issues for trial of the '514 patent may be completed in 42 hours split evenly between Plaintiffs and Defendants.

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of December 16, 2019. To the extent that it would be helpful, the parties are available to discuss scheduling via teleconference at the Court's convenience.

Further details regarding the parties' availability are noted below.

B. Details Regarding Plaintiffs' Witnesses' Availability

Plaintiffs reached out to their expert and fact witnesses after receiving the Court's order on November 13th. All witnesses from whom Plaintiffs have received a response have conflicts with the week of December 2, 2019. Three of Plaintiffs' expert witnesses are unavailable. First, Dr. Daniel Wynn, a neurologist, has a full schedule of patients to see during the week of December 2nd. Second, Dr. Martin Duddy, also a neurologist, and Mr. John Jarosz, an economist, both have preexisting professional commitments during the week of December 2nd. Additionally, one of Biogen's fact witnesses, Dr. Katherine Dawson, has a preexisting professional commitment in her role as Biogen's Senior Vice President of Development during the week of December 2nd. Plaintiffs are awaiting a response from their remaining witnesses on availability during the week of December 2nd.

C. Details Regarding Defendants' Witnesses' Availability

Defendants have contacted each of their four anticipated trial witnesses. Three of Defendants' witnesses have a conflict with preexisting professional engagements for the week of December 2, 2019. Drs. John Lindsey and Gary Stobbe are treating neurologists, who have previously scheduled appointments with patients, including patients in ongoing clinical trials that need to be seen in a defined time period. Dr. Wee Yong is a Professor at the University of Calgary, who has preexisting professional commitments with his faculty and a visiting professor, including planned travel for work. Defendants' fourth trial witness, Mr. Ivan Hofmann, can be available for trial in the second half of the week of December 2, 2019, but at least a portion of Mr. Hofmann's role will be in rebuttal to Plaintiffs' expert Mr. John Jarosz, who Plaintiffs have stated is not available the week of December 2, 2019.

Respectfully,

/s/ Steven J. Balick

Steven J. Balick (#2114)

SJB/mlk

cc: All Counsel of Record (via electronic mail)